REMARKS

Applicants have amended the claims in order to more particularly define the invention taking into consideration the outstanding Official Action. Claim 21 has been added to more particularly define the invention. Basis for this new claim may be found on page 18, lines 28-30, and former claim 17. Applicants most respectfully submit that all the claims now present in the application are in full compliance with 35 U.S.C. §112 and are clearly patentable over the references of record.

The rejection of claims 2 and 4-9 under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,575,795 has been carefully considered but is most respectfully traversed.

Applicant wishes to direct the Examiner's attention to MPEP § 2131 which states that to anticipate a claim, the reference must teach every element of the claim.

> "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed.Cir. 1990).

The Examiner has referred specifically in this regard to column 1, lines 49-60, of US 5,575,795 which is said to teach a method of autologous transplantation of healthy mature lymphocytes obtained from mature non-diseased human blood in support of this rejection.

The passage cited in the Official Action refers to the use of "**placental** blood for autologous transfusions" as well as to the use of "specific elements from **placental** blood".

The Examiner is most respectfully asked to note that the disclosure of the use of placental blood (and umbilical cord blood) is specifically excluded from the scope of the claims of the present application by virtue of the reference in current claim 2 to the fact that "the cells are obtained from the host **organism**". Placenta and umbilical cord are not a "host organism".

In particular, the Examiner is referred to page 13, lines 12-14, of the current application which specifically defines a host organism as being "the post-natal body". Furthermore, page 13, lines 15-16, specifically states that "the umbilical cord and placenta are not included".

Thus it can be seen that the current claims do not lack novelty in the light of the disclosures of US 5,575,795. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 11, 14 and 16 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,575,795 in view of U.S. Patent No. 5,876,321 has been carefully considered but is most respectfully traversed.

The Examiner has cited the above provision against the non-obviousness of claims 11, 14 and 16 in the light of the disclosures of US 5,575,795 in view of US 5,876,321.

The relevance of US 5,575,795 has been discussed above under 35 U.S.C. 102(b) and this discussion is equally applicable to the present rejection. The passage cited by the Examiner refers only to the use of placental and umbilical cord blood, and makes no reference or teaching whatsoever towards the use of non-placental or non-cord blood.

Furthermore, the invention disclosed in US 5,575,795, relates solely to an "umbilical cord holder" and hence the skilled person would not have considered this document to have any relevance to inventions relating to autologous transplantation therapy using non-umbilical cord cells.

The Examiner is respectfully reminded that WO89/04168 (which was previously cited) also discloses the isolation and preservation of various foetal and neonatal cells

from blood; and that there were specific teachings in that document **away** from the use of "mature, healthy lymphocyte cells". This was discussed in detail Applicants amendment filed on June 2, 2004 (top of page 7) herein incorporated by reference.

In particular, WO89/04168 stated:

> "... the use of **neonatal cells** for hematopoietic reconstitution according to the present invention **provides distinct advantages** over the employment of **adult peripheral blood**" (page 22, line 33, to page 23, line 2).

The Examiner accepted the teachings of the above document as directing the skilled person away from the use of mature healthy lymphocytes.

Consequently, it can be seen that there are no specific disclosures in US 5,575,795 towards the use of any blood cells other than placental or umbilical cord blood cells; and that there were specific teachings in the prior art against the use of cells from non-neonates. On this basis, it is respectfully asserted that the person skilled in the art would **not** have combined the disclosures of US 5,575,795 with any documents that refer to the transplantation of patients with **non-neonatal cells** since to do so would have been directly contradictory to the teachings of the prior art. The teachings of the prior art must be considered as a whole and this includes teaching away from the claimed invention. The necessary motivation to modify the prior art to arrive at the claimed invention must be found in the prior art and Applicants' claims may not be used as a teaching reference for this motivation.

The Examiner is asked to note that it was not previously known in the prior art to take mature, healthy lymphocytes from a **non-diseased** individual and then to use them for autologous transplantation. The prior art disclosures (including those of US 5,876,321, as discussed further below) refer **only** to the treatment of **patients who are already diseased**.

The Examiner has asserted that US 5,876,321 teaches the freezing of autologous white blood cells for later use in the treatment of cancer. The Examiner has

referred particularly to column 1, lines 48-64. The passage cited by the Examiner starts:

> "Blood components may be collected from a **patient**, stored and perhaps frozen and reinfused into the patients **days** or even years **later**. The mononuclear cell portion of white blood cells is sometimes collected, stored in the above manner, and reinfused into the **patient for the treatment of diseases such as cancer** ...".

Autografting was well known in the relevant prior art and it is discussed, for example, on pages 5-6 of the current application.

The above-quoted passage is clearly referring to organisms that are **already diseased**. This is evident from the references to "a patient" and "the patient". Furthermore, the above-quoted passage clearly envisages the reinfusion of the cells to the patient within a defined time-span, for example, "days ... later". Reinfusion might occur, for example, after treatment of the patient with chemo- or radio-therapy. This is to be contrasted with the current invention which refers specifically to "cells which are obtained from blood of said organism when **non-diseased**".

It must also be appreciated that US 5,876,321 makes no specific disclosure of the advantages to be gained in the transplantation of a host organism with healthy, mature lymphocyte cells.

It is respectfully asserted therefore that the disclosures of US 5,575,795 cannot be said to teach or suggest the subject matter of the current claims; the prior art previously cited by the Examiner teaches away from the use of mature, healthy lymphocytes; and the disclosures of US 5,876,321 relate only to the treatment of patients which are already diseased. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 11 and 15 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,575,795 in view of Abe et al. has been carefully considered but is most respectfully traversed.

The Examiner has cited the disclosures of US 5,575,795 when viewed in the light of Abe *et al.* (1996) against claims 11 and 15. The Examiner has asserted that Abe *et al.* teaches the use of genetically modified lymphocytes in cancer therapy and that such cells have improved anti-tumour activity. The Examiner has referred in this regard to page 165, Results.

The relevance of US 5,575,795 to the patentability of the current claims has been discussed above. It has been shown therein that this document refers merely to the removal of white blood cells from **placental** blood for storage and possible future administration to the patient or relative as an alternative to a bone marrow transplant. Claims to such subject matter are specifically excluded from the scope of the current invention; prior art cited previously by the Examiner specifically teaches away from the use of non-neonatal cells.

Abe *et al.* (1996) refers to the use of CTLs from murine B16 melanomas. Such cells were transduced with human adenovirus type 5 with expression cassettes containing murine interferon-gamma cDNA. These CTLs were subsequently transferred to mice with B16 lung tumours.

Abe *et al.* (1996) makes no reference whatsoever to the obtaining of mature healthy lymphocyte cells from a host organism when non-diseased and the subsequent autologous transplantation of the host organism with such cells. The disclosures of Abe *et al.* are therefore entirely immaterial to the patentability of the current claims, when combined with the disclosures of US 5,575,795 or not. Accordingly, it is most respectfully requested that this rejection be withdrawn.

Applicants note that the Examiner has returned and initialed the forms 1449 in connection with the Information Disclosure Statements filed. However, Applicants request clarification with respect to the references which are both initialed and in which have lines drawn through them. Applicants most respectfully request this clarification as to whether these references have been made of record in the next official action.

In view of the above comments and further amendments to the claims, favorable reconsideration and allowance of all of the claims now present in the application are most respectfully requested.

Respectfully submitted,

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